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Grace J. Fishel
11970 Borman Drive, Suite 220
St. Louis, MO 63146

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,070,080

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,070,080, which claims the methods of use of the animal drug product Neutersol® (zinc gluconate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

Applicant also has applied for patent term extension of U.S. Patent No. 4,937,234 based on the regulatory review period for the animal drug product Neutersol®.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to this requirement for election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration or election, the Director will issue a certificate of extension in the first issued patent for which patent term extension was sought, i.e., U.S. Patent No. 4,937,234, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of (69 Fed. Reg. 40944), would be 2,079 days (5.7 years). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (4,188 days- 99 days) + 34 days
	=	2,079 days (5.7 years)

Since the regulatory review period began August 27, 1991, before the patent issued (December 2, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 27, 1991, to and including December 3, 1991, is 99 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,070,080
Granted:	December 3, 1991
Original Expiration Date[1]:	December 3, 2008
Applicant:	Mostafa S. Fahim
Owner of Record:	Technology Transfer, Inc.
Title:	METHOD OF INHIBITING GENERATION, MATURATION, MOTILITY AND VIABILITY OF SPERM WITH MINERALS IN BIOAVAILABLE FORM
Product Trade Name:	Neutersol® (zinc gluconate)
Term Extended:	5 years
Expiration Date of Extension:	December 3, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: Neutersol® (zinc gluconate)
FDA Docket No.: 03E-0405

[1]Subject to the provisions of 35 U.S.C. § 41(b).